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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/731,867 | 12/09/2003 | Carl D. Wahlstrand | 1023-336US01 | 6722 |

28863 7590 09/07/2007

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|---|---|
| REIDEL, JESSICA L | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3766 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 09/07/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/731,867 | WAHLSTRAND ET AL. | |
| | Examiner | Art Unit | |
| | Jessica L. Reidel | 3766 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *14 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-24,26-31,33 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24,26-31,33 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/07, 8/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. Acknowledgement is made of Applicant's Amendment, which was received by the Office on June 14, 2007. Claims 25 and 32 are cancelled. Claim 34 is new and has been added. Claims 1-24, 26-31 and 33-34 are pending.

### *Information Disclosure Statement*

2. The information disclosure statements (IDS) submitted on January 30, 2007 and August 16, 2007 have been acknowledged and are being considered by the Examiner.

### *Oath/Declaration*

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application, by application number and filing date, is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> It does not correctly state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

Specifically, the oath or declaration does not have the correct statement with respect to the duty to disclose. This applies to all applications, not just reissue applications. The Examiner suggests obtaining the most recent version of the PTO/SB/01 which states, "I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application".

***Specification***

4. The specification contains reference to commonly owned patent applications without application numbers and/or without stating the current status of each application. The Examiner respectfully requests that this information be updated along with any other referenced applications without application numbers, or any referenced applications that have since issued or since been abandoned.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. ***Claims 23-24 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanchez-Zambrano (U.S. 5,895,414).*** As to Claim 23, Sanchez-Zambrano discloses a concave elliptical pacemaker, read as an implantable medical device comprising a housing 11 that includes an outer surface 13, 15 that is concave along at least two axes such that the surface conforms

substantially to an arc (see Sanchez-Zambrano Figs. 2-3, column 1, lines 58-67 and columns 2-3). It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation, but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. In the instant case, the outer surface 13, 15 of the housing 11 of the pacemaker of Sanchez-Zambrano is capable of being implanted on or recessed into a cranium of a patient.

Sanchez-Zambrano expressly discloses the claimed invention, as discussed above, except it is not specified that the arc be within a range from 4.5-9.5 centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the arc from 4.5-9.5 centimeters, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Sanchez-Zambrano discloses the claimed invention, as discussed above, except that it is not specified that housing 11 of the pacemaker be metallic. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the housing metallic, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin,* 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

8. As to Claim 24, Sanchez-Zambrano discloses the claimed invention as discussed above except that it is not specified that the arc be approximately equal to 7 centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the arc 7 centimeters, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch,* 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

9. As to Claim 26, Sanchez-Zambrano discloses that the surface of the housing 11 comprises a first surface 13 and a second surface 15. Sanchez-Zambrano further discloses that second surface 15 is adapted to be implanted distal from the implantation site and conforms substantially to the arc – specifically, second surface 15 is convex (see Sanchez-Zambrano, entire document). It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation, but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. In the instant case, the second surface 15 of the housing 11 is capable of being implanted distal from the cranium.

10. As to Claim 27, Sanchez-Zambrano discloses that the implantable medical device (i.e. the concave elliptical pacemaker) comprises conventional pacemaker electronics and power source within housing 11 (see Sanchez-Zambrano Abstract and column 2, lines 40-43). It is inherent, or at least obvious to one having ordinary skill in the art, that "conventional pacemaker electronics" typically include a therapy delivery circuit, such as a pulse generator and control electronics to control delivery of the stimulation by the therapy delivery circuit. The Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Conventional pacemaker electronics, as discussed, are capable of "delivering stimulation to the brain of the patient".

11. ***Claims 23-24 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Probst et al. (U.S. 2003/0017372) (herein Probst).*** As to Claim 23, Probst expressly discloses an implantable medical device 10 comprising a metallic housing 36 that includes an outer surface that is adapted to be implanted on or recessed into a cranium of a patient (see Probst pages 1-2, paragraphs

3-4 and 16-20) where the surface of the housing 36 is concave along at least two axes such that the surface conforms substantially to an arc (see Probst Figs. 1-4 and 6-8, page 2, paragraphs 20-24 and page 3, paragraphs 35-41). Probsts specifies that the is a need for a housing 36 of an implantable medical device that is shaped or contoured to more closely fit the curved shape of the body, such as the skull, read as the cranium (see Probst page 1, paragraph 3). Probst expressly discloses that one embodiment of housing 220 comprising a first curved portion 226 defined by radius R2 and a second curved portion 232 defined by radius R3 and a third curved portion 236 defined by radius R4 where R2, R3 and R4 may have different degrees of curvature (see Probst Fig. 7 and page 3, paragraphs 37-38). Probst further discloses an embodiment of housing 250 where the housing 250 is concave along at least three axes such that the surface conforms to an arc where three radii of curvature (R5, R6, R7) are substantially equal (see Probst Fig. 8 and page 3, paragraphs 40-41). Probst discloses the claimed invention as discussed above except it is not specified that the arc be within a range from 4.5-9.5 centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the arc from 4.5-9.5 centimeters, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

12. As to Claim 24, Probst discloses the claimed invention as discussed above except that it is not specified that the arc be approximately equal to 7 centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the arc 7 centimeters, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch,* 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

13. As to Claim 26, Probst discloses that the surface of the housing comprises a first surface of the housing and a second surface of the housing that is adapted to be implanted distal from the

cranium. Upon inspection of Probst Figs. 1-4 and 6-8, it is clearly depicted that both surfaces are manufactured to conform substantially to an arc (see Probst pages 1-2, paragraphs 20-24 and page 3, paragraphs 36-42).

14. As to Claim 27, Probst discloses that the implantable medical device 10 may be an implantable neurostimulator. It is inherent, or at least obvious to one having ordinary skill in the art, that "a neurostimulator" as well known in the art, typically includes a therapy delivery circuit, such as a pulse generator and control electronics to control delivery of the stimulation by the therapy delivery circuit. The Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Conventional neuorstimulator electronics, as discussed, are capable of "delivering stimulation to the brain of the patient".

15. ***Claims 1-11, 13-14, 16-22, 28-31 and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell (U.S. 3,888,260) in view of Probst.*** As to Claims 1-6, 10-11, 13-14, 18, 22 and 33, Fischell expressly discloses an implantable medical device (IMD) comprising a plurality of interconnected modules, each of the modules comprising a respective one of a plurality of housings (see Fischell Figs. 1a-1b and Figs. 2-3). Specifically, the IMD comprises pulse generation circuitry to deliver a stimulation therapy to a brain of a patient, read as therapy delivery element and control electronics to control the delivery of the stimulation (i.e. pulse duration, frequency, amplitude) by the therapy delivery element, where the therapy delivery element and control electronics are located within a module housed by inner casing or can 13 (see Fischell column 1, lines 44-68, column 2, lines 1-3, column 3, lines 67-68, column 4, lines 1-53, column 12, lines 67-68 and column 13, lines 1-17). The IMD further comprises a rechargeable power source module

comprising a rechargeable battery, read as a power source located within its own housing 19 (see Fischell column 5, lines 15-25 and column 6, lines 40-49). Each of the housings 13, 19 are horizontally distributed at respective locations of an overmold, where the overmold comprises a flexible Silastic compound 19a, a stainless steel outer can 18 and a flexible coating 27. Upon inspection of Fischell Figs. 2-3, it is clear that housings 13, 19 are separately encapsulated by at least flexible portion 19a of the overmold of the IMD and completely encapsulated by stainless steel potion 18 and flexible coating portion 27 of the overmold, in addition to being horizontally distributed in a linear configuration (see Fischell Figs. 2-3, column 4, lines 54-68, column 5, lines 1-12 and lines 60-68 and column 6, lines 1-28). Fischell discloses the claimed invention, as previously discussed, except it is not specified that a surface of the overmold is concave along two axes, prior to manipulation of the IMD, such that the surface is adapted to be implanted proximate the cranium of the patient and adapted to conform substantially to the cranium.

Probst, however, teaches an IMD 10 (i.e. a neurostimulator, pacemaker, defibrillator) housing comprising opposed major sidewalls 62, 64 of a contoured shape (see Probst Figs. 1-4 and 6-8) and an inner power source module 12 housing 14, also having opposed sidewalls 16, 18 of a contoured shape (see Probst Fig. 1) such that areas of the body, such as the skull, do not have to be invasively and/or unnecessarily excavated in order to facilitate implantation of the IMD. Specifically, the IMD 10 of Probst comprises a housing, read as an overmold manufactured such that opposing surfaces of the overmold conform substantially to an arc, where at least a first surface is concave along multiple axes and the second opposing surface is convex and distal from the first surface and the implantation site (i.e. the cranium). The overmold of Probst conforms substantially to an arc (see Probst Figs. 7-8 and page 3, paragraphs 36-42) prior to manipulation of the IMD 10 such that the surfaces are adapted to be implanted proximate to a cranium, to conform substantially to the cranium (see Probst Abstract,

pages 1-2, paragraphs 2-4 and paragraphs 21-24). IMD 10 of Probst also comprises housing 14 of module 12, identical to that of the overmold of the entire IMD (see Probst page 1, paragraphs 16-19). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the housings of modules 13, 19 and the overmold as taught by Fischell, so that a surface of at least one of the housings 13, 19 is manufactured as concave along multiple axes and a surface of the overmold is concave along multiple axes, such that the overmold conforms substantially to an arc, prior to manipulation of the IMD, in order to provide an improved IMD adapted to be implanted proximate the cranium of the patient, to conform substantially to the cranium and further such that the IMD that may be easily implanted without undo excavation of the implant site as taught by Probst.

16. As to Claims 7, 19, 30-31 and 34, the previously modified Fischell reference discloses the claimed invention, as previously discussed, except that it is not specified that the arc be within a range from 4.5-9.5 centimeters. Since Probst expressly discloses that the device may be implanted proximate the skull, on or within the skull, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the arc from 4.5-9.5 centimeters, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

17. As to Claims 8-9 and 20-21, the previously modified Fischell reference discloses the claimed invention, as discussed above, except that it is not specified that the arc be approximately equal to 7 centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the arc 7 centimeters, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

18. As to Claim 17, the rechargeable power source module of Fischell is interconnected to a multi-turn insulated winding, read as a recharge coil that is wound around a ferrite material/substrate to form transformer 20 for inductively receiving energy to recharge the power source within housing 19 (see Fischell Figs. 2-3, column 5, lines 13-31, column 6, lines 40-68 and column 7, lines 1-23). The previously modified Fischell reference discloses the claimed invention as previously discussed except that it is not specified that both the housing of the rechargeable power source module and the coil be manufactured to be concave along two axes. Since Probst teaches that it is desirable, as previously discussed, for both the inner modules and the housing/overmold of an IMD to comprise at least a first surface that is concave along multiple axes in order to provide an improved IMD that substantially conforms to the site of implantation, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Fischell such that the housings 13, 19, the ferrite material of transformer 20 and the overmold are concave prior to manipulation of the IMD, in order to provide an improved IMD adapted to be implanted proximate the cranium of the patient, to conform substantially to the cranium and further such that the IMD that may be easily implanted without undo excavation of the implant site as taught by Probst.

19. As to Claim 16, the previously modified Fischell reference discloses the claimed invention as previously discussed except that it is not specified that the power source module include a battery with a foil pack construction. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the rechargeable power source module of Fischell such that its battery has a foil pack construction since it was known in the art that foil-pack constructed batteries are light-weight, biocompatible and relatively flexible (i.e. non-brittle).

20. As to Claims 28 and 29, Fischell expressly disclose that housing 13 is metallic and hermetic (i.e. nickel or gold) (see Fischell column 4, lines 26-53). It is inherent that housing 19 of the

rechargeable power source module, comprising rechargeable nickel-cadmium power source, is hermetic, since a hermitic housing 19 is necessary in order to keep the battery electrolyte from leaking throughout the interior cavities of the IMD (see Fischell column 4, lines 16-27 and column 5, lines 13-31). Fischell does not however, expressly disclose that the material of housing 19 comprise a metallic material, however, it is inherent that the housing is metallic since the power source is nickel-cadmium and since flexible and insulating portion of overmold 19a is required. In the alternative, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the housing 19 metallic, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin,* 227 F.2d 197, 125 USPQ 416 (CCPA 1960). Furthermore, Probst teaches that it is well known in the art to house an electrochemical power source 12 of an IMD within a conductive housing 14 comprising a metallic material such as nickel, aluminum, stainless steel, mild steel, tantalum and/or titanium such that the housing 14 may be used as an anode/cathode in a unipolar embodiment (see Probst page 1, paragraphs 16-18). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the housing 19 of the rechargeable power source module of Fischell such that it is made from a conductive metallic material, as taught by Probst in order to provide an IMD that may use the housing of its power source to operate in a unipolar configuration.

21. ***Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell in view of Probst as applied to claims 1 and 13 above, and further in view of Faltys et al. (U.S. 6,308,101) (herein Faltys).*** The previously modified Fischell reference discloses the claimed invention as previously discussed except that it is not specified that the rechargeable power source module, having housing 19 and a rechargeable battery power source include a battery power source with a would coil

construction. Faltys, however, teaches that it is known in the art to use a recharging coil 220 of an IMD, not only for recharging a rechargeable battery power source of the IMD and for enabling bi-directional telemetry communication with an external device, but to also use the coil 220 to provide power for operating the device during recharging, or when the rechargeable battery power source fails (see Faltys column 15, lines 27-65 and column 19, lines 25-61). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the inductive coil of the transformer interconnected with the rechargeable power source module of Fischell in view of Probst such that the coil acts as a battery in order to power the IMD during recharging and/or when the rechargeable battery within housing 19 reaches the end of its life.

***Double Patenting***

22. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

23. ***Claims 1-10, 12-24, 26-31 and 33-34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 7,212,864.*** Although the conflicting claims are not identical, they are not patentably distinct from

each other because the current claims are either an obvious broadening of the scope of the patented claims or an obvious variant thereof. As to Claims 1, 12, 23 and 30 of the current application, U.S. Patent No. 7,212,864 also claims an implantable neurostimulator device comprising a plurality of interconnected modules, each module comprising a respective one of a plurality of housings where at least a portion of each of the housings extends out of a flexible overmold where the portion of each of the housings that is/are not encapsulated by the overmold are adapted to be implanted proximate to the cranium of the patient. U.S. Patent No. 7,212,864 further specifies that the overmold of such a device be shaped for implantation on a cranium. Similar analysis may be applied to the remaining dependent claims of the current application upon inspection of conflicting and patented Claims 1-23 of U.S. Patent No. 7,212,864. In regards to any missing features, not expressly claimed by U.S. Patent No. 7,212,864, the Examiner cites references to Fischell, Probst, Faltys and Sanchez-Zambrano and notes that application of the teachings of these references to the conflicting and patented Claims 1-23 of U.S. Patent No. 7,212,864 parallel their application(s) in the 35 U.S. 103(a) rejections, previously set forth in this Office Action.

24. ***Claims 1-24, 26-31 and 33-34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 and 17-55 of U.S. Patent No. 7,242,982.*** Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either an obvious broadening of the scope of the patented claims or an obvious variant thereof. As to Claims 1, 23 and 30 of the current application, U.S. Patent No. 7,212,864 also claims an implantable neurostimulator device comprising a plurality of interconnected modules, each module comprising a respective one of a plurality of housings, where a flexible, concave overmold multi-component overmold at least partially encapsulates each of the housings and is concave to conform substantially to a cranium of a patient. Similar analysis may be applied to the

dependent claims of the current application upon inspection of conflicting and patented Claims 1-16 and 17-55 of U.S. Patent No. 7,242,982. In regards to any missing features, not expressly claimed by U.S. Patent No. 7,242,982, the Examiner cites references to Fischell, Probst, Faltys and Sanchez-Zambrano and notes that application of the teachings of these references to the conflicting and patented Claims 1-16 and 17-55 of U.S. Patent No. 7,242,982 parallel their application(s) in the 35 U.S. 103(a) rejections, previously set forth in this Office Action.

25. ***Claims 1-24, 26-31 and 33-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21, 23-31, 33-37, 39-40, 42-53 and 55-61 of copending Application No. 10/731,869 (Amended June 8, 2007).*** Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either an obvious broadening of the scope of the patented claims or an obvious variant thereof. As to Claims 1, 11-12, 23 and 30 of the current application, Application No. 10/731,869 also claims an implantable neurostimulator device comprising a plurality of interconnected modules, each module comprising a respective one of a plurality of housings where at least a portion of each of the housings extends out of a flexible overmold where the portion of each of the housings that is/are not encapsulated by the overmold are adapted to be implanted proximate to the cranium of the patient. Application No. 10/731,869 also claims an alternative embodiment where the overmold completely encapsulates each of the housings and in both embodiments claimed in Application No. 10/731,869, the overmold is shaped for implantation on a cranium. Similar analysis may be applied to the remaining dependent claims of the current application upon inspection of the conflicting and pending Claims 1-21, 23-31, 33-37, 39-40, 42-53 and 55-61 of copending Application No. 10/731,869. In regards to any missing features, not expressly claimed by Application No. 10/731,869, the Examiner cites references to Fischell, Probst, Faltys and Sanchez-

Zambrano and notes that application of the teachings of these references to the conflicting and pending Claims 1-21, 23-31, 33-37, 39-40, 42-53 and 55-61 of copending Application No. 10/731,869 parallel their application(s) in the 35 U.S. 103(a) rejections, previously set forth in this Office Action.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Response to Arguments***

26. Applicant's arguments with respect to claims 1-11, 13-14, 16, 18-22 and 28-33 have been considered but are moot in view of the new ground(s) of rejection, necessitated by Applicant's Amendments submitted June 14, 2007.

27. Applicant's arguments filed June 14, 2007, with respect to the rejection(s) of Claims 23-24 and 26-27 under 35 U.S.C. 103(a) as being unpatentable over Sanchez-Zambrano (see page 16 of the Remarks), have been fully considered but they are not persuasive. Applicant argues that Sanchez-Zambrano teaches an acrylic housing therefore, to make the housing metallic would not have been prima facie obvious because a metallic housing would not provide the same advantages with respect to device weight as an acrylic. The Examiner respectfully disagrees and notes that although Sanchez-Zambrano discloses that top mounting portion 33 of the device is preferably made from acrylic and further that side mounting portions 37 of the device are also, preferably made from acrylic in order to minimize potential for infections (see Sanchez-Zambrano column 1, lines 15-18 and column 2, lines 16-39), Sanchez-Zambrano does not disclose or merely suggest that any portion of housing 11 (i.e. interior/bottom surface 13 and/or exterior/top surface 15) be made from acrylic or comprise acrylic. Additionally, the lightweight desirability for the device, as disclosed by Sanchez-

Zambrano at column 3, lines 25-26, does not preclude one of ordinary skill from choosing a metallic material for the device housing. The Examiner provides O'Pehlan et al. (U.S. 5,876,424) (herein O'Phelan) as evidence that it is well known in the art of implantable medical devices, particularly implantable pacemakers and/or defibrillators, to choose hermetic case/housing 62, 102 formed from a number of materials, such as titanium and stain-less steel, where the case/housing 62, 102 seals the device and provides structural integrity as known in the art, while also providing an improved implantable medical device of reduced size and volume (see O'Phelan column 1, lines 53-67, column 2, lines 1-48, column 3, lines 35-59 and column 5). As discussed in the Office Action of January 17, 2007 and above in this Office Action, the selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). See MPEP § 2144.07.

In response to Applicant's argument that Sanchez-Zambrano does not teach or suggest any range of radii of curvature, the Examiner respectfully disagrees. At column 1, lines 61-63, Sanchez-Zambrano expressly discloses that the housing 11 "has a uniform thickness of 1 to 3 milimeters but tapers smoothly near the periphery to a radius of curvature of 0.4 to 0.6 millimeters". In response to Applicant's argument that because the device of Sanchez-Zambrano preferably contours to the natural curvature of the patient's ribs 25 and 27, an optimal range or value of radius of curvature – as defined by the limitations of Applicant's claims 23 and 24 – would not have been prima facie obvious to one having ordinary skill in the art. The Examiner respectfully disagrees and provides Ostroff et al. (U.S. 2002/0107546) (herein Ostroff) as evidence that it is well known in the art to manufacture concave/contoured implantable medical devices such that they vary in length and/or curvature in order to accommodate patients of various anatomical sizes and Ostroff further shows that it is well known in the art for a concave/contoured device to substantially conform to the

curvature of the ribs of a patient where the radius of curvature of manufactured devices may vary from about 5 cm to about 35 cm, depending on the size of the patient. Ostroff expressly discloses that because there are many different sized of people, the housing of an implantable medical device should come in different incremental sizes to allow a good match between the size of the rib cage and the size of the device (see Ostroff pages 6-7, paragraphs 57 and 63). Since the device of Sanchez-Zambrano preferably contours to the natural curvature of the patient's ribs 25 and 27, discovering the optimum or workable radius of curvature for housing 11 would have been prima facie obvious to one having ordinary skill in the art given the typical and known rib curvature of patients, as known in the art or given typical and discovered rib curvatures of patients found via routine experimentation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP § 2144.05.

28. Applicant's arguments filed June 14, 2007, with respect to the rejection(s) of Claims 23-24 and 26-27 under 35 U.S.C. 103(a) as being unpatentable over Probst (see page 17 of the Remarks), have been fully considered but they are not persuasive. Applicant argues that Figs. 1-4 and 6-8 of Probst only show concavity along one axis. The Examiner respectfully disagrees and notes that the embodiments shown in Probst Figs. 6-8 are identical to those of Applicant's Figs. 8A-8B and 9A-9B depicting concavity along more than one axis. The Examiner is unsure how the embodiments of Probst, clearly depicted in Figs. 6-8, only show one axis of curvature, when the depictions of the prior art and Applicant are the substantially the same view of a concave/contoured device. Furthermore, at page 3, paragraphs 36-42, Probst expressly discloses that concavity may be along at least three axes and further that the curvatures defined by R2, R3 and R4 of the embodiment of Probst Fig. 7 may be different from one another and the curvatures defined by R5, R6 and R7 of the

embodiment of Probst Fig. 8 may be substantially equal. Probst further specifies that there may even be only two axes or more than three at page 3, paragraph 39).

Applicant further argues that Probst does not specify a radius of an arc of the housing be within a range from 4.5 to 9.5 centimeters or approximately equal to 7 centimeters. Since Probst expressly discloses that the device may be implanted on or within a skull, arm, or leg, as discussed in the Office Action of January 17, 2007 and above in this Office action, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the arc from 4.5-9.5 centimeters, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art. *In re Aller*, 105 USPQ 233. It also would have been obvious to one having ordinary skill in the art at the time the invention was made to make the arc 7 centimeters, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch,* 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

***Conclusion***

29. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

30. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The Examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jessica L. Reidel/
Patent Examiner, Art Unit 3766
August 27, 2007

/Kennedy J. Schaetzle/
Primary Examiner, AU 3766
August 30, 2007